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REMARKS

The Office Action of April 19, 2007, has been carefully considered.

Objection has been raised to the specification and claims based upon the manner of identifying amino acid sequences. While Applicants do not actually believe that the specification and claims contained "typographical errors" in this regard, but only a difference in style, Applicants have nevertheless amended the specification as well as the claims to use the terminology identified in the Office action.

In addition, Claims 79, 84, 95 and 99 have been amended to remove the other cited objections.

Applicants do not believe that Claim 99 is a duplicate of Claim 97, since Claim 99 depends from Claim 79, whereas Claim 97 depends from Claim 92.

Claims 79, 84, 87, 92, 97, 98 and 99 have been rejected under 35 USC 112, second paragraph, as being indefinite.

Claims 79 and 92 have been amended to recite the α-cyclodextrin derivative in the preamble, thus providing antecedent basis for the term in the definition of the derivative. Moreover, variables A1, A3 and A5 have been replaced by their definitions.

Withdrawal of this rejection is requested.

Claim 87 has been rejected under 35 USC 112, first paragraph, on the basis that the specification lacks support for preventing prostate cancer or benign prostatic hypertrophy. Claim 87 has been amended to delete the term "or prevention," and the withdrawn Claims 88, 89, 90 and 91 have similarly been amended to delete "or prevention."

Withdrawal of this rejection is requested.

Claims 79, 82, 94, 87, 92, 95, 97, 98 and 99 have been rejected under 35 USC 103(a) over Hirai et al in view of Kurihara et al and Kano et al.

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Hirai et al discloses a composition for nasal, vaginal or rectal preparations containing an LR-RH analog together with α-clodextrin or a derivative. The Office action states that non-oral administration routes are taught as the "preferred" methods of administration. Indeed, Hirai et al teach against oral administration of LR-RH analogs, and as such, is representative of the art, as cited in the present application at page 1, last paragraph. There is no disclosure or suggestion that such drugs should or can be administered orally, but rather they should be administered, according to the Hirai et al, nasally, vaginally or rectally. The Office action further states that Hirai et al allows an inference that an oral administration method was employed with "reduced success," but this phrase used in the Office action implies that some success with oral administration has been achieved, a conclusion submitted by Applicants to be unwarranted. As noted in the present specification, satisfactory oral administration has not been reported, and Hirai et al similarly states that the oral administration method is not adequate, and that the compositions of the Hirai et al invention are far improved. It does not appear that Hirai et al has any interest at all in the oral administration of LR-RH analogs with cyclodextrin; the reference certainly does not suggest oral administration of LR-RH analogs combined with cyclodextrin.

Kurihara et al teaches that cyclodextrin may be used to improve the solubility of cyclosporins, which are peptides. Such peptides have particular physical features in that they are hydrophobic, have a cyclic structure and have a molecular weight greater than 1200. There is no disclosure or suggestion in Kurihara et al that cyclodextrin should be combined with *the peptides of the invention*, in order to improve biological activity. Applicants submit that it is not

a reasonable inference that because cyclodextrin improves the solubility of cyclosporin, that it will also improve the biological activity of the compounds of the invention. Given the differences between the LR-RH analogs of the claimed invention and the cyclosporin of Kurihara et al, and further given all the factors mentioned specifically in the Office action with regard to *In re Wands*, Applicants submit that the art is not sufficiently predictable to arrive at the inference made in the Office action.

The Kano et al article relates to a mechanism for binding to the flexible cavity of permethylated α-cyclodextrin, and properties of this compound are compared to those of ortho-toluic acid or para-toluic acid. There is no disclosure or suggestion of α-cyclodextrin derivatives enhancing the biological activity of the LH-RH analogs.

Thus, there is nothing in the cited art to suggest that the claimed α-cyclodextrin derivatives will improve the biological activity of the specific peptide analogs of Claims 79 and 92.

Withdrawal of this rejection is requested.

In view of the foregoing amendments and remarks, Applicants submit that the present application is now in condition for allowance. An early allowance of the application with amended claims is earnestly solicited.

Respectfully submitted,

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